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Original paper

A novel radiographic technique to asses grafts in the female pelvis: a comparison of the Inside-Out and the Outside-In trans-obturator mid urethral sling positioning

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Abstract

The three-dimensional configuration of mid-urethral sling tapes is difficult to demonstrate in traditional anatomical dissections or imaging studies. The aim of this study was to test the utility of a novel technique using mesh tapes to assess spatial differences between the *in-out* and *out-in* transobturator mid-urethral slings. Two independent surgeons performed their usual transobturator mid-urethral sling placement on 10 fresh thawed cadavers, alternating sides in the consecutive cadavers. Tantalum wires threaded through the polypropylene-tapes rendered them radio-opaque. Following placement, CT scans were obtained to generate 3-D and MIPS images for analysis. Results showed that the mean angle formed by the *in-out* sling measured 122º (95%CI: 107º-136º); versus 144º (95%CI: 131º-151º) for the *out-in* sling (p = 0.02). The paired differences between the tapes' inner angles were significantly different; with a mean difference of 20º (median 19.0º), (*p* = 0.008). There was no significant correlation between either approach and BMI or angle of the pubic arch. The images revealed that the tapes lie as a band posterior/dorsal to the urethra rather than inferior. In conclusion: marking mesh with Tantalum wire, in combination with 3-D and MIPS CT-scan reconstruction images, provided a unique method to visualize the entire sling trajectory. The clinical implications of the more horizontal positioning after the out-in approach remain to be determined.

Key words: **Urinary incontinence, anatomy, TVT-O, TOT, transobturator tape, imaging.**

Aim of the study

The transobturator approach to treat female stress urinary incontinence by means of a midurethral sling (MUS) placement was first described by Delorme to potentially prevent complications associated with the retropubic MUS placement originally described by Ulmsten (Delorme, 2001; Ulmsten et al., 1996). A similar transobturator passage utilizing an inside-out approach, as opposed to Delorme's outside-in approach, was later described by de Leval, aiming to further reduce the potential injury to the urethra and bladder (de Leval, 2003).

A recent meta-analysis found similar cure rates between the 3 most commonly used surgical approaches for treating stress urinary incontinence, namely the retropubic, outside-in transobturator, and inside-out transobturator MUS procedures (Latthe et al., 2010). Multiple studies have discussed the anatomical trajectories of both obturator approaches and confirmed their anatomical safety from a neurovascular perspective (Bonnet et al., 2005; Achtari et al., 2006; Hinoul et al., 2007; Zahn et al., 2007; Reisenauer et al., 2006). The large body of clinical evidence supports these findings.

To date, anatomical studies have focused on the MUS's trajectory in relation to the obturator foramen, the muscles and especially the neuro-vascular structures. Traditional anatomical dissections do not allow the study of the MUS's configuration in

relation to the urethra, as a progressive dissection of the entire tape's trajectory would be required, inherently leading to a distortion of the relevant anatomy. The aim of this cadaveric study was to compare the specific relationship between the tape and the urethra in both the inside-out and outside-in approach. To allow such a comparison, CT-scan image analysis was performed after Tantalum wire marked mesh slings were implanted in a series of cadavers.

Materials and Methods

The study was undertaken using 10 fresh frozen, unembalmed female cadavers after thawing. Bodies were donated to the institution for scientific research purposes. No Institutional Review Board was required.

All 10 cadavers were operated upon, by independent surgeons, one experienced with the 'Inside-Out' (*In-Out*) and one with 'Outside-In' (*Out-In*) MUS technique. Cadavers were positioned in the dorsal supine lithotomy position with the legs in abduction and at a 100° flexion position (at the level of the hips) on the In-Outside and at 90° flexion on the Out-In side. The surgical technique for the transobturator MUS procedures were performed according to the instructions for use as provided by the respective manufacturers (*Out-In*: Monarc™ , American Medical Systems, Minnetonka, MN and *In-Out*: TVT™ -Obturator System, Ethicon Inc., Somerville, NJ). All cadavers were catheterized using a Foley catheter with its lumen filled with a radio-opaque solution (HypaqueMeglumine 60%, Amersham Health, Princeton, NJ) to allow subsequent identification of the urethral position. Both the *In-Out* and the *Out-In* transobturator procedures were performed on each cadaver, alternating the type of procedure and tape between the right and left sides in the consecutively operated cadavers. To be able to do this with a single tape in each cadaver, a device was conceived for this study in which the tape on one side consisted of an *In-Out* MUS device, while an *Out-In* MUS device was attached to the other side at the midpoint. To allow radiographic visualization of these tapes, a double Tantalum wire was threaded through each side of both midurethral tapes as shown in Figure 1. This design allowed for an intra-cadaveric comparison between 10 independent *In-Out* transobturator MUS trajectories and 10 *Out-In* transobturator MUS trajectories. Care was taken to have a flat positioning of both tape ends at the end of the procedures. Tensioning was performed using a Metzenbaum scissor between the urethra and the tape. The vaginal incision sites were closed and the MUS tapes were cut 2 cm from the level of the skin. To exclude the possible influence of the surgeon's right handedness, an equal number of both procedures was performed on the right and left sides; both surgeons were right handed. BMI of the cadavers ranged between 15 and 33 kg/m^2 (mean: 25.3; median: 26). Each cadaver subsequently underwent supine CT-Scan (GE Medical System). Scanning parameters were 2 SCOUTS axial contiguous with overlapping slice thickness at 0.5mm. Post capture image analysis was performed using the Vitrea Core 5.1.1618.1808 Image Analysis software (ViTAL, 5850 Opus Parkway, Suite 300, Minnetonka, MN 55343-4414). Multiple In Plane Section (MIPS) cuts were used to get a "coronal cut" plane that included the urethra at the point where it crossed the urethra and the two arms of the sling extending from the urethra to the point where it crossed the obturator membrane. This was done to prevent parallax effects that might alter the measured angle (Hoyte and Ratiu, 2001). On the MIPS view of the images, the relative angulations between a line through the urethral axis and the slope drawn through each MUS tape's mean upward pathway (forming the hammock part of its trajectory) were measured (Table I). The angle inside the upward

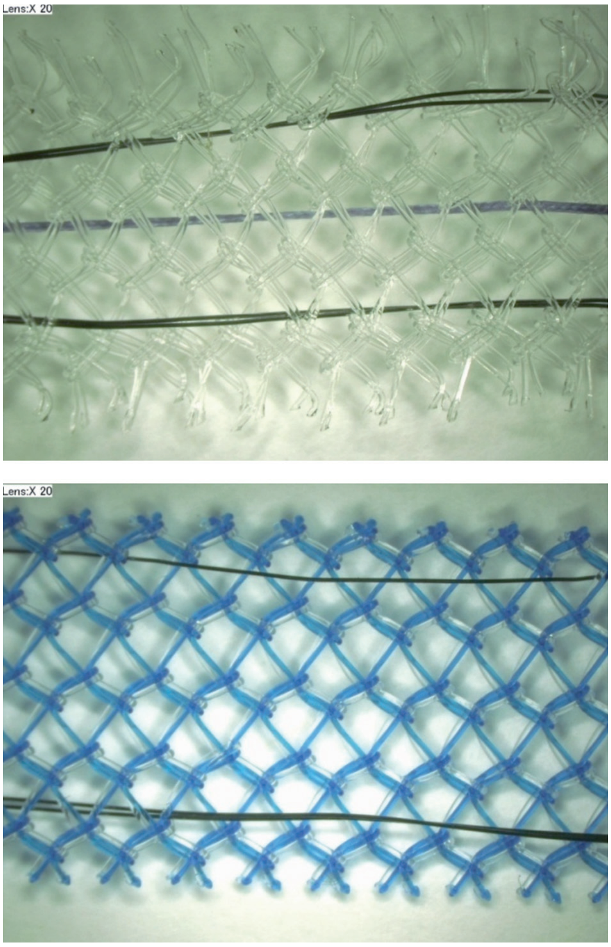

Fig. 1. — 'Outside-In' (above) and 'Inside-Out' (below) midurethral sling including a double Tantalum wire threaded through to allow radiographic visualization.

Table I. — Mid-urethral sling inner angles.

Procedure #	Inner angle Outside-In Tape	Inner angle Inside-out Tape	BMI	Pubic Arch Angle
1	138	110	24	81
2	144	126	24	97
3	122	102	27	84
4	126	114	25	94
5	122	102	NR	81
6	144	144	26	76
7	150	90	34	75
8	162	140	27	74
9	156	138	27	82
10	148	148	15	78
Mean	141 (SD14)	121 (SD10)	25	82

trajectory of the tape constituted the angle under consideration for this study and is referred to as the tape's hemi inner angle, as only half a procedure was performed on each cadaver (Fig. 2b). For the study's purposes the assumption was made that a symmetric, bilateral placement of a full length tape would yield the full inner angle of the MUS hammock corresponding to double the hemi-inner angle measurement.

Statistical analyses

Statistical analyses were performed using the Wilcoxon Signed-Rank test for matched paired data for non-parametric testing of 2 dependent samples.

Results

All cadavers were deemed to have normal vaginal tissue quality. Three cadavers were noted to have stage 2 prolapse and 1 had a notably high vaginal sulcus. The 3-dimensional CT images revealed that the MUS tapes lie as a band posterior/dorsal to the urethra rather than inferior. These findings are illustrated in Fig. 2a-c. The *out-in* MUSs were more closely wrapped around the inferior ischio-pubic ramus than the *in-out* MUSs. Qualitative assessment of the images demonstrated a safe distance from the tapes to the obturator canal for both techniques. Distances of the tapes' trajectories to the individual obturator nerve branches could not be determined.

The mean full inner angle in a strict antero-posterior view formed by the *in-out* MUS measured 122° (95%CI: 107°-136°); versus 144° (95%CI: 131°-151°) for the *out-in* MUS ($p = 0.02$). The (paired) differences between the tapes' inner angles were significantly different; with a mean difference of 19.8° (median 19.0°), (Wilcoxon Signed Rank Test: $p = 0.008$). Correlation analysis only showed a trend between the *out-in* and the *in-out* MUS angle (Correlation coefficient: 0.6, $p = 0.08$). A similar trend was observed between the patient's BMI and the *in-out* MUS angle (Correlation coefficient: 0.6, $p = 0.08$), but not for BMI and the *out-in* MUS angle (Correlation coefficient: 0.08, $p = 0.8$). There was no correlation between the infra-pubic angle measurement and the *out-in* MUS angle nor the *in-out* MUS angle.

Discussion

The use of Tantalum wires threaded through the polypropylene-/ prolene-tape in combination with three-dimensional CT-scanning yielded a unique method to visualize midurethral tapes throughout the entirety of their trajectory. This technique can be applied to different types of non radio-opaque implants, allowing for a better spatial understanding of the anatomical position within the pelvis. This technique circumvents the technical problems encountered by ultrasound where visualization is partially obstructed by the bony pelvis and the fact that traditional anatomical techniques rely on a progressive dissection intrinsically only allowing visualization at a single level each time.

This is the first controlled anatomical study to compare the spatial relationships between the *in-out* and *out-in* MUS tapes and the female urethra. The difference could be objectified by measuring the angle formed between the two legs of the MUS tape. The *in-out* approach angulated around the urethra in a more acute fashion than the *out-in* approach, which seemed to follow a more horizontal,

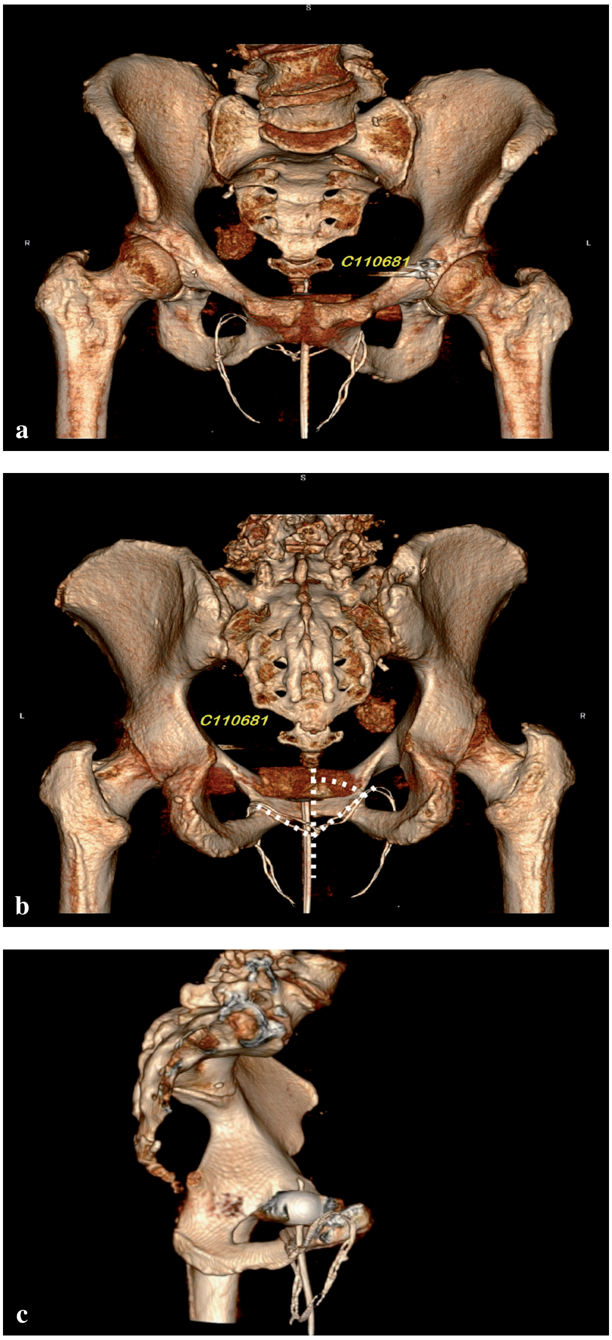

Fig. 2. — 3-D CT Scan images
2a. Ventro-dorsal view (frontal view; L = Left, R = Right). Outside-in tape on left, Inside-out tape on right.
2b. Dorsoventral view (view from behind). Outside-in tape on left, Inside-out tape on right.
Note: dotted lines schematically demonstrates the hemi-inner angle but do not correspond to the MIPS view used to measure the actual angles.
2c. Right sagittal view. Outside-in tape on left, Inside-out tape on right.

flatter, trajectory (122° versus 142°). These findings were counter-intuitive as the exit-points of both devices at the level of the skin would suggest the opposite.

The three dimensional radiographic visualization of the tape's trajectory also allowed for an appreciation of the MUS tapes' spatial configuration in relation to the bony pelvis and the urethra. Contrary to the belief that the urethra is suspended in a cranially directed U-shaped band, both obturator MUS approaches were demonstrated to be U-shaped bands that head backwards or dorsally. The tape is not positioned caudally but lies as a band behind the urethra, suggestive of its passive (non obstructive) role in achieving continence.

As observed in the different measurements of the tapes' angles, there seemed to be a higher variability in the in-out's than the out-in trajectory (58° versus 40° variation respectively), as previously described by Hinoul et al. in a traditional anatomic study, underscoring the need for strict adherence to the prescribed operative technique (Hinoul et al., 2007).

The strength of this study was that the cadavers could be their own control. The importance of this becomes clear when comparing it to two ultrasound studies investigating the angles formed by the two arms of MUS tapes. Lin et al described an angle at rest for the *in-out* tape to be 115° (SD13°) while Chene et al, measured the same angle at rest also using ultrasound to be 138°(SD7°) (Lin et al., 2012; Chene et al., 2007). The differences in outcomes obtained in these studies demonstrate that (inter- and intra-individual) comparisons may prove to be difficult to interpret. The cadaveric study design was also the study's limitation as no clinical findings could be correlated to the static anatomic findings.

A direct meta-analysis comparing both routes of transobturator tapes by Madhuvrata et al. (2012) reported no significant differences in the objective and subjective efficacy but showed that the "inside-out" route was associated with significantly fewer vaginal angle injuries but with a non-significant-trend towards higher risk of postoperative groin pain. In a small retrospective study, *out-in* MUS tapes were more frequently associated with a finding of superficial placement at the level of the lateral vaginal sulcus, described as paraurethral banding (Cholhan et al., 2010). Coincidentally, the only cadaver with a notably high vaginal sulcus was found to have a very palpable *out-in* MUS tape post placement. Increased rates of dyspareunia and tape exposures after the *out-in* compared to the *in-out* approach have been reported upon by Elzevier et al. (2008) and Scheiner et al. (2012), but these finding were not confirmed in an RCT by Abdel-Fattah et al. (2010). The more horizontal positioning of the *out-in* tape's trajectory, taking the mesh closer to the vaginal wall, as described in this study could explain these clinical observations. The radiographic images explain the increased risk of 'button-holing' during an *out-in* procedure because the more acute *in-out* MUS trajectory buries the tape deeper inside the internal adductor muscles. On the other hand,

this study also confirmed that the *out-in* MUS trajectory stayed closer to the ischiopubic ramus. The slightly more lateral *in-out* MUS trajectory causes the tape to be seated in more muscular tissue. The corresponding inflammatory reaction might explain the trend to a slightly higher risk of transient thigh pain.

The clinical implications from this cadaveric imaging study are that surgeons must pay more attention to the 2nd half of the helical pass, whichever way they chose to go. For the *in-out* passage, one must rotate hard and carefully around the ischiopubic ramus and not get lazy with the rotation; while for the *out-in* pass, care must be taken that dissection of the peri-urethral tunnel provides for a full thickness vaginal epithelial layer. Future studies will have to explore the clinical relevance of these findings. The advent of three-dimensional ultrasonography will allow for similar measurements of the different tapes' trajectories in vivo in a dynamic setting, possibly allowing correlation of these findings to nuances in clinical outcomes. Ultrasound will not be able to provide the same holistic visualization within the bony pelvis, but mesh-tape beyond the obturator membrane probably does not contribute to the MUS functional effect or possible adverse events at the level of the vagina. Recently, a new approach, incorporating iron particles into polymer-based implants, allowed in vivo visualization of mesh by magnetic resonance imaging (MRI) following inguinal hernia surgery (Hansen et al., 2013). Approval of these types of products for human use in the future will bring new insights into the action mechanism of mesh in the pelvic floor as well as a better understanding of the mesh- tissue interaction.

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